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FOR HHS SECRETARY LEAVITT FROM CDA STEVEN WHITE
HHS PASS TO NIH
STATE PASS TO USAID
STATE FOR SCA; OES (STAS FEDOROFF); OES/PCI STEWART; OES/IHA SINGER
PASS TO HHS/OGHA (STEIGER/HICKEY), CDC (BLOUNT/FARRELL),
NIH/FIC (GLASS/MAMPILLY), FDA (LUMPKIN/WELSCH, GENEVA FOR HOFMAN)

SENSITIVE
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SUBJECT: SCENESETTER PART III: THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) SECRETARY LEAVITT'S JANUARY 7-11, 2007 VISIT TO INDIA

REF: (A) 2007 New Delhi 5418

(B) 2008 New Delhi 0008

NEW DELHI 00000022 001.2 OF 016

¶1. (SBU) Summary: This is the third scenesetter cable, which provides information and analysis on government authorities that exist and are being created for regulation of drugs, food, medical devices, and biotechnology. This is a long cable and our intent is to provide "complete picture" for your briefing book of the regulatory environment for drugs and food as well as information and analysis of import safety. This cable also provides views of the private sector as far as needs for transparent regulatory authorities are concerned. Finally, we provide information and analysis on import safety and our suggested talking points for meetings with the Prime Minister and other Indian Ministers you will be meeting during your five-day visit to India. Reftels A and B provided information on political, economic, life sciences, health sciences, and pubic health aspects of the US-India relationship. End Summary.

¶2. (SBU) Your visit and its focus on import safety has attracted attention and interest at governmental and industry levels. Mission has requested meetings with the Prime Minister and Ministers of Health and Family Welfare, Science and Technology, Agriculture, Commerce, and External Affairs. In Chennai, you will speak at an event hosted by the Southern Region chapter of the Confederation of Indian Industries (CII). CII is inviting leaders and academics from southern Indian states involved in life sciences, health sciences, biotechnology, and health care. In Delhi, you will speak at an event organized by the Federation of Indian Chambers of Commerce and Industries (FICCI). FICCI is inviting leadership of pharmaceutical and food exporters for this event. This will be your opportunity to engage with industry leaders on the topic of import safety.

¶3. (SBU) We believe that Government officials will listen and agree to cooperate on import safety, but the record of Indian regulatory

authorities is not good. The Indian officials will tell you that Indian products are safer as compared to China, which is more of a "we are better than China" sentiment than reality. On the other hand, industry leaders from the drug and food sector, who are eager to listen to you, understand the importance of establishing standard operating procedures for the safety of consumer products. There are sensitive and confrontational trade issues with the seafood and general export industries, which may come up in your meetings with the Agriculture and Commerce Ministers or with FICCI.

¶4. (SBU) We believe that government and industry trade organizers will inform you that they intend to set up in-house, state-of-the-art laboratories for testing products, and would request FDA support for setting up these laboratories. The GOI would like to "test its way to food safety", if possible. We urge you to emphasize that any safety testing should be backed up by a functional regulatory system and done by GOI accredited, independent laboratories that uses accepted protocols and methodologies. Finally, we propose you state that best available science, methodology, and practices should be used in testing and trade-related decision making. Considering the fact that India and the United States are science and knowledge-based economies, our partnership on import safety can be a model for other bilateral and multilateral collaborations.

PLANS TO ESTABLISH CENTRAL DRUG AUTHORITY OF INDIA (CDA)

¶5. (SBU) India's existing drug regulatory infrastructure does not adequately perform assigned functions efficiently and promptly. The Drug Controller General of India (DCGI) in the Central Drugs Standard Control Organization (CDSCO) lacks in-house scientific and technical expertise required to evaluate new drugs, vaccines, devices, and recombinant products and is heavily dependent on external evaluations such as from the Indian Council of Medical Research (ICMR), the Department of Biotechnology (DBT) and other external experts. This poses a problem as sensitive information is

shared with external reviewers without any agreements on confidentiality.

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¶6. (SBU) At present, product approvals are granted by both central and state-level regulatory authorities. Disparity in regulatory/licensing standards among different states and their non-compliance with DCGI's directions throw up a variety of issues such as proliferation of irrational drugs, misbranding (retaining the brand name after change of ingredients), circumvention of regulatory procedures for launch of new drugs, etc. Pharmaceutical companies have the freedom to approach any of the licensing authorities. If the drug licensing authority of a particular state happens to reject an application, the company can get the same approved from another state and yet market the product all over the country (a drug manufactured in one state moves freely in inter-state commerce).

¶7. (SBU) With an objective to streamline the fragmented regulatory practices of different states and bring uniformity to the licensing process across India, the Government of India, in January 2007, gave its nod for creation of an autonomous Central Drug Authority (CDA) of India. The move followed the proposals made by several expert bodies including the Mashelkar Committee which pitched for a comprehensive revamp of the drug regulatory system in the country.

SALIENT FEATURES OF CDA

¶8. (SBU) The CDA will be an autonomous center located at the Food and Drug Bhawan, New Delhi under the Ministry of Health and Family Welfare (MOHFW). The authority would be modeled on the lines of the United States' Food & Drug Administration (U.S.-FDA) with a completely centralized licensing system under the Union Government. It is expected that the CDA will have a three-to-five member board under the Chairmanship of an eminent scientist, which would handle

policy decisions. It will have separate divisions for oversight of regulatory affairs and enforcement, imports, new drugs and clinical trials enforcement, biologicals and biotechnology products, pharmacovigilance, medical devices and diagnostics, organizational services, training, quality control affairs and legal & consumer affairs.

¶9. (SBU) The executive wing of the regulator would be headed by the Drugs Controller, who will be a Secretary level official (Note. Secretary in the GOI system is highest level policy maker in the

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Ministry. End Note). However, each division overseeing defined activities pertaining to drugs and cosmetics research and commercialization would be largely independent. The authority would be financially self-sustaining. It would devise a fee structure for its regulatory services, the proceeds from which would be utilized to meet its capital spending and day-to-day expenses. The CDA would also get the power to prosecute clinical research organizations, investigators and pharmaceutical companies violating respective rules and regulations (including manufacture and marketing of spurious drug products). CDA would closely interact with the drug watchdogs abroad to harness regulatory expertise. It has been proposed that the centralized system of drug manufacture and licensing will be instituted through a phased transition over a period of five years.

FUNCTIONS OF CDA

¶10. (SBU) Ministry of Health and Family Welfare has proposed the following functions for the Central Drug Authority;

- Licensing of drug manufacturing units
- Registration of pharmaceutical products
- Quality control of imported drugs
- Post marketing surveillance
- Control on medical devices
- Control on diagnostics

- Control on nutraceuticals, food supplements and herbal products
- Guidelines for promotional literature
- Promotion of rational use of drugs
- Guidelines for self medication
- Monitoring of clinical trials and bio-equivalence studies
- Monitoring of adverse drug reactions
- Interaction with consumers and handling of complaints
- Central nodal intelligence cum legal cell to coordinate inter-state activities
- Training of regulatory and laboratory personnel

¶11. (SBU) The Health Minister has stated that the CDA will be modeled on the lines of the U.S. Food and Drug Administration (FDA). In meetings with the Mission Health Attach, the Health Minister requested technical support from HHS/FDA for governance, structure and functioning of FDA. Health Attache has conveyed this request to HHS and FDA officials. After discussion with HHS and FDA, Health Attach suggested to the Minister that the Ministry submit a proposal with a plan of action, so that FDA staff can review it and respond. The MOHFW outreach to HHS/FDA indicates its appreciation of the U.S. systems of review and approval that are established by HHS/FDA. HHS/FDA support will ensure the development of a regulatory body that utilizes science-based decision making, transparency, and effective reporting.

¶12. (SBU) Since the announcement establishing the CDA by the Minister about a year ago, the movement on the ground for establishing this authority has been slow. Ministry officials have informed Health Attach that the cumbersome procedures at the Ministry and approvals needed from other Ministries are causing delay in getting legislative authority for establishing this authority.

PLANS TO ESTABLISH NATIONAL BIOTECHNOLOGY REGULATORY AUTHORITY

(NBRA)
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¶13. (SBU) India is emerging as a significant biotechnology hotbed in the Asia Pacific region. Although relatively small in size at the moment, India's biotech industry is growing at a phenomenal rate of more than 35 percent per annum. India's human health biotech firms are rapidly attaining critical mass in terms of skills and capabilities to produce biogeneric products and vaccines. India is also becoming a hub for global outsourcing of contract research and contract manufacturing. According to Department of Biotechnology (DBT), biotechnology as a business segment for India has the potential of generating revenues to the tune of USD seven billion by ¶2010.

CURRENT REGULAT0RY FRAMEWORK FOR BIOTECHNOLOGY PRODUCTS
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¶14. (SBU) The current regulatory framework for biotechnology products in India is weak, complex and time-consuming. The approval process involves several poorly coordinated regulatory agencies falling under different GOI Ministries. In addition, there is a lack of expertise in dealing with biologicals on the part of these regulatory agencies. The biotechnology industry perceives this as a major obstacle that delays product development and can potentially stifle the budding biotech sector in India. At present, the following GOI organizations comprise the framework for evaluation, approval and regulation of biotechnology products in India:
- Drug Controller General of India (DCGI) under the Ministry of Health and Family Welfare
-Review Committee on Genetic Manipulation (RCGM) under Department of Biotechnology, Ministry of Science and Technology
- Genetic Engineering Approval Committee (GEAC) under the Ministry of Environment and Forests

¶15. (SBU) Keeping in view the rapid strides being taken in the area of agro- and food biotechnology research and application and the

critical need to harmonize/streamline guidelines and procedures for approving genetically engineered products, the GOI proposes to establish the National Biotechnology Regulatory Authority (NBRA). At present India does not permit the import or sale of genetically modified foods and only one biotech crop is approved for domestic production (cotton).

SALIENT FEATURES OF NBRA

¶16. (SBU) The NBRA will be an autonomous, independent, and professionally led single window agency for biosafety clearance of genetically modified products and processes in India. The Authority would be headed by a scientist well known for expertise in biotechnology and biosafety assessment and will have representatives from all the relevant stakeholders. It will be housed under the Department of Biotechnology of the Ministry of Science and Technology. It is expected that a budget of USD 1.6 billion (INR 65 billion) would be made available to the Department of Biotechnology during the Eleventh Plan for implementing the National Biotechnology Development Strategy (which includes the establishment of the NBRA) (Note: DBT's current budget is approximately USD 360 million. End Note).

¶17. (SBU) NBRA will have separate divisions for biopharmaceutical products, agriculture/transgenic crops, industrial products, transgenic food/feed and transgenic animal/aqua culture. It will also be responsible for setting up policy guidelines and ensuring need based periodical evaluation of the regulatory mechanism. It will update all existing guidelines and put in place guidelines for transgenic research and product/process development in animal, aqua culture, food, phyto-pharma and environmental applications. NBRA will have a Standing Advisory Committee consisting of nominees of State Governments, so as to maintain close liaison with State Governments in matters relating to the release and monitoring of genetically modified strains of crops, farm animals and fish. An advanced school of learning will be a part of the NBRA in order to

ensure adequate in-service training and updating for regulatory personnel engaged in this fast evolving field.

CURRENT STATUS

¶18. (SBU) Following several weeks of discussion and negotiations with the Ministry of Health and Family Welfare, consensus has emerged that NBRA should be housed under the Department of Biotechnology (DBT) of the Ministry of Science and Technology. Secretary DBT has informed Health Attach that the decision for DBT

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to house the NBRA was made at the Prime Minister's office level. DBT has initiated the preparation for setting up this Authority by inviting expression of interest from external agencies/consultants. Secretary DBT has informed Health Attach that the Government of

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India would like to work closely with U.S. regulatory bodies such as the Food and Drug Administration (FDA), U.S. Environmental Protection Agency (EPA) and U.S. Department of Agriculture (USDA).

¶19. (SBU) The NBRA Bill is expected to be introduced in the 2008 budget session of the Parliament after getting Cabinet approval. According to Dr MK Bhan, Secretary DBT, NBRA is expected to be fully functional in about two years. Secretary Bhan is known to be a data-driven professional who keeps (and forces staff) to keep to timelines. Therefore, it is likely that this authority may be established within the proposed timeline. However, the competing interests and "ownership" issues from other Ministries (Ministry of Agriculture and Ministry of Environment) may derail this DBT initiative.

PLANS TO ESTABLISH MEDICAL DEVICE REGULATORY AUTHORITY (MDRA)

¶20. (SBU) Several biomedical devices and critical care equipment are being used in India for diagnostic and therapeutic purposes. In

addition, a number of research organizations and private entrepreneurs are showing active interest in the development and manufacture of medical devices in India. Unfortunately, the Indian market for medical devices is poorly regulated. The country lacks a comprehensive regulatory framework for certification, quality assurance, safety evaluation and post-market surveillance of medical devices.

¶21. (SBU) With an objective to ensure that at least certain devices meet accepted quality norms, the Ministry of Health and Family Welfare, has from March, 2006, included select medical devices (10 sterile devices including cardiac and drug eluting stents) under the definition of medical drugs, thus putting them under the purview of the Drug and Cosmetic Act. This notification entrusted the Central Drugs Standard Control Organization (CDSCO) under the Drug Controller General of India (DCGI) with the responsibility of regulating these devices in India (this is an additional responsibility for CDSCO over and above its primary function of laying down regulations and standards for import, manufacture and sale of drugs, blood products, intravenous fluids, vaccines, diagnostics and cosmetics). The CDSCO now has guidelines that stipulate that all importers of select medical devices need to apply for import licenses and file product registrations with the DCGI. These applications must include such documentation as the master file, detailed product information, post-marketing surveillance procedures, and safety and quality system standards for the device.

¶22. (SBU) However, several medical devices continue to remain unregulated. While imported devices have come under the purview of the Drug and Cosmetic Act, locally manufactured and non-sterile devices continue to be sold freely in the market. Some low-technology devices like thermometers and weighing machines seek certification from the Bureau of Indian Standards (BIS) and that too is optional.

EVENTS PERTAINING TO REGULATION OF MEDICAL DEVICES

¶23. (SBU) The creation of the Indian Medical Devices Regulatory Authority (IMDRA - as the apex body for the implementation of the country's regulatory system for biomedical devices) was proposed by the Indian Council of Medical Research (ICMR) and the Society for Biomedical Technology (SBMT - an inter-ministerial organization set up under the Defense Research and Development Establishment with the objective to utilize defense research spin offs for healthcare) several years ago. SBMT sponsored a review of the existing certification procedures and regulatory mechanisms in other countries and on the basis of the information compiled by the review, it conceptualized a framework for regulation of medical devices in India.

¶24. (SBU) In 2004, the Mashelkar Committee called for the creation of a specific medical devices division within the Central Drugs Standard Control Organization (CDSCO) to address the management, approval, certification and quality assurance of all medical devices in India.

¶25. (SBU) In October, 2005, the Ministry of Health and Family Welfare declared that select medical devices (cardiac stents, drug eluting stents, catheters, intra-ocular lenses, intravenous cannulae, bone cements, heart valves, scalp vein sets, orthopedic implants, and internal prosthetic replacements) be considered as medical drugs under the Drug and Cosmetic Act. It was also notified that control over import and manufacture of these devices would be exercised by the Drug Controller General of India (DCGI).

¶26. (SBU) The U.S.-India Business Council (USIBC - comprised of more than 300 U.S. companies with investment interests in India and about 25 global Indian companies) hosted a U.S.-India High Technology Cooperation Group (HTCG) meeting in February 2007. At this meeting, attended by both U.S. and Indian government

representatives, discussions on medical devices were included for the first time and it was decided to spearhead a joint private-sector working group dedicated to issues facing the medical device industry in India, foremost the development of a regulatory regime for medical devices.

¶27. (SBU) In early 2007, the Ministry of Health and Family Welfare proposed to create a new national drug authority called Central Drug Authority (India). It was communicated that this new authority will have a dedicated division for medical devices.

¶28. (SBU) In September, 2007, the Department of Science & Technology, within the Ministry of Science and Technology, proposed to bring in new legislation to enforce uniform and effective standards of medical devices throughout the country. The objective of this initiative is to ensure that substandard devices are not exported, especially to developing countries, which do not have medical device regulation in place. The government also proposed to create a regulatory authority that will seek to establish and maintain a national system of certification relating to quality, safety, efficacy and availability of medical devices.

MEDICAL DEVICES REGULATION BILL

¶29. (SBU) The objectives of the bill are to consolidate laws related to medical devices in India and to establish the Medical Device Regulatory Authority of India (MDRA) for establishing and maintaining a national system of controls relating to quality, safety, efficacy, and availability of medical devices used in India (whether produced in India or elsewhere) and exported from India. The primary function of MDRA would be to regulate and monitor the design, testing and evaluation, manufacture, packaging, labeling, import, sale, usage and disposal of medical devices, to ensure availability of safe medical devices for human use in the country.

¶30. (SBU) MDRA shall specify standards that will form the basis for

the conformity assessment of the medical devices. It shall be binding on manufacturers of medical devices to conform to the essential principles of safety and performance and to demonstrate conformity before placing the medical devices on the market or export from India. Manufacturers shall be liable to allow the MDRA to carry out necessary inspections and also to supply it with all relevant documentation.

STATUS OF MEDICAL DEVICES REGULATION BILL

¶31. (SBU) The Department of Science and Technology has published the draft version of the Medical Devices Regulation Bill on its website (http://www.dst.gov.in/whats_new/main-new.htm). The medical device industry has been requested to provide comments and suggestions for its improvement as well as both positive and negative impact of the same on the industry. At present, Biomedical Technology Wing, Sree Chitra Tirunal Institute for Medical Sciences and Technology is coordinating and compiling the feedback being received from the Industry. Following, this Bill is expected to be tabled in the parliament.

PLANS TO ESTABLISH FOOD SAFETY AUTHORITY

¶32. (SBU) The Government of India has announced plans to establish a single food safety agency in 2008 under the Ministry of Health and Family Welfare. Currently, India has multiple, overlapping laws and entities that regulate food safety. There are more than 20 laws relating to food safety and roughly 14 implementing agencies. Many of the sanitary laws were drafted soon after Independence under conditions very different from today; when trade was small and adulteration was the primary concern.

¶33. (SBU) With a highly fragmented national structure -- spread

across a minimum of three central government ministries -- food import and export safety controls are handled via different systems and by separate Ministries. Many food safety rules are "on the books" but not observed in practice. Multiple laboratories are jockeying for the position of being "the" export certification or pre-clearance laboratory. The issuing of inspection certificates (including self-certification or producer group certification) is a frequent, but unregulated practice. This overlapping, bureaucratic and fragmented system allows for officials to avoid responsibility and significant trade takes place in the unorganized sector.

¶34. (SBU) The Ministry of Health and Family Welfare was of the view that the Food Safety Authority will be established in 2007. However, Ministry of Health has had to deal with several controversial issues in 2007, which has led to delay in setting up this new authority. The Secretary of Health and Family Welfare, Naresh Dayal, has stated that "setting up this authority is a top priority". He has also requested technical support from FDA and USDA for this initiative. At present, the new food safety authority is in limbo, and there is no single counterpart agency equivalent to FDA.

PRIMER ON FOOD SAFETY?

¶35. (SBU) Import safety - including food and agricultural products - has been discussed at both the technical and political level in the U.S.-Indo Trade Policy Forum (TPF). The TPF is a Presidential initiative, chaired by the U.S. Trade Representative and the Indian Ministry of Commerce. With a generally defensive posture, the GOI's actions on import safety and trade are highly political and generally "top-down." In recent negotiations on import safety, the Indian side took their "case to the media" and leaked inaccurate and denigrating information on U.S. imports to the local press in advance of bilateral talks.

¶36. (SBU) India's food and marine products industries have evolved considerably since the 1950s and exporters today - especially of spices, cashews and shrimp-are politically well organized and highly

sensitive to perceptions of negative quality or safety issues. Suggestions of retaliation are frequent knee-jerk reactions to "foreign" claims of poor food safety and quality in India. Public charges of lax food safety provoke very strong, defensive political reactions from the Indian government and related industries. India is currently struggling with European Union (EU) concerns about dioxin, pesticide residues and other import safety issues - with Indian industry groups claiming the EU's requirements are market access barriers put up by developed countries seeking to discriminate against emerging economies like India. Requests for data are rejected as "excessive" and the GOI has claimed in official forums, such as CODEX committees, that they should not be held to the same standards as the U.S. and EU.

¶37. (SBU) Old and outdated pesticides and veterinary drugs are still used in India because companies are reluctant to register new products due to lax data protection. The GOI defends domestic use of "old" farm chemicals and inability to meet international standards as a condition of their developing country status and frequently points to their "livelihood" issue (needing to protect its small/marginal farmers and companies). The over-use of banned antibiotics by aquaculture farmers threatens the reputation of seafood exporters and the central government has little ability to enforce standards or inspections.

¶38. (SBU) The government of India's use of modern food safety practices is limited. India's domestic food producers and processors are subject to more relaxed regulations. Imports of foreign food products to India are highly regulated and taxed. The U.S. maintains a 4:1 trade imbalance in food and agriculture, with India shipping USD 1.4 billion to the U.S. (mainly shrimp, cashews, spices and tea) while the U.S. exported only USD 370 million in food/agriculture products to India in 2006. The U.S. recently

granted market access to Indian mangoes after much work on various protocols and safety issues. However, India refuses to allow in U.S. wheat and dairy products, for example claiming that our products are not safe or clean enough.

¶39. (SBU) The Ministries of Commerce, Health and Agriculture -together with domestic industry associations-have a role in regulating export food safety. However, the government of India, mainly through the Ministry of Commerce, depends heavily on the Export Inspection Council (EIC) to administer pre-shipment inspections. The EIC in turn works with semi-public industry bodies to administer both export promotion and ad hoc safety programs. The EIC is not directly linked to either the laws or systems administered by the Ministries of Agriculture and Health.

¶40. (SBU) For example, the Ministry of Commerce's Agriculture and Processed Food Products Export Development Authority (APEDA) is responsible for promotion and development of India's food and agriculture export industries. APEDA registers exporters; establishes export standards, specifications; certifications and quality parameters. Shrimp and seafood exports are administered and promoted by the Marine Products Export Development Authority. The Ministry of Commerce also promotes and regulates exports of tea, spices, coffee, rubber and tobacco through statutory industry boards. Similarly, the spices export is promoted and regulated by the Spices Board of the Ministry of Commerce, which is based in Cochin.

ISSUES RELATED TO EXPORT OF SHRIMP TO THE U.S.
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¶41. (SBU) On December 31, 2003, the Southern Shrimp Alliance (composed of shrimp industry groups from Alabama, Florida, Georgia, Louisiana, Mississippi, North Carolina, Texas, and South Carolina) filed antidumping petitions with the Commerce and the International Trade Commission (ITC) against imports of frozen and canned warm-water shrimp from Brazil, China, Ecuador, India, Thailand, and Vietnam. As a result of U.S. Department of Commerce (Commerce) and ITC actions, imports of frozen warm-water shrimp from India, as well as China, Brazil, Ecuador, Thailand and Vietnam, are subject to antidumping duties with margins ranging from four to 24 percent for

participating companies.

¶42. (SBU) In July 2004, Customs and Border Protection (CBP) authorized ports to impose increased bond requirements in connection with antidumping (AD) and countervailing (CV) duties on agriculture and aquaculture goods. CBP has for a number of years required importers to post bonds as security for compliance with customs and other regulations. The bond requirement applies in addition to existing bonds and cash deposits. Following the final affirmative antidumping determination by Commerce in February 1, 2005, CBP imposed a substantially higher bond requirement on importers of shrimp from the above mentioned countries.

¶43. (SBU) The Indian Government is concerned that the continuous bonding requirement imposed by U.S. CBP is an excessive financial burden on importers of Indian shrimp. CBP imposed the continuous bonding requirement in response to concern from Congress and others that importers were avoiding payment of antidumping and countervailing duties. The Indian Government requested the establishment of a WTO panel to review the consistency of the continuous bonding requirement with our WTO obligations. On April 24, 2006, Thailand requested consultations with the United States, followed by India on June 6, 2006. Consultations were held on July 31 and August 1, 2006, with additional discussions thereafter. While India's complaint is limited to the bonding issue, Thailand additionally challenged Commerce's use of so-called "zeroing" to calculate weighted average dumping margins in the shrimp case.

¶44. (SBU) Thailand and India principally alleged that the imposition of the continuous bond requirement on importers of shrimp constitutes "specific action against dumping" not in accordance with

the WTOAD Agreement. (Note: They also argued that the bond requirement breaches various other provisions of the AD Agreement. End Note.) The panels found that the additional bond requirement, as applied to importers of shrimp from India and Thailand, was "specific action against dumping" not in accordance with Articles of the Antidumping Agreement. As part of their analysis of this claim, the panels concluded that the requirement did not constitute "reasonable" security permitted by the AD.

¶45. (SBU) The panel addressing India's claim also found that: I) the United States had acted inconsistently with Article 7.2 of the AD Agreement (which limits security prior to imposition of an order to the dumping margin established in the preliminary determination) insofar as it applied the directive to a small number of importers of shrimp from India prior to imposition of the order; and II) the United States had acted inconsistently with Article 18.5 of the AD Agreement and 32.6 of the SCM Agreement because it had failed to notify the directive to the AD and SCM Committees.

¶46. (SBU) Under WTO rules, such interim reports are confidential, and are not final. Parties have the opportunity to file comments and there is the option for either party to appeal. It is unfortunate that someone has chosen to breach the WTO rules and publicly comment on the confidential interim report. The panel in its interim report did not agree with the United States that the bond requirement as applied to Indian and Thai shrimp was not inconsistent with the AD Agreement and constituted reasonable security. The panel report is not yet final, and the U.S. side will be submitting comments on the interim report to the panel. The disputing parties (the United States, India, and Thailand) have an opportunity to submit comments on the interim report. The panel was scheduled to issue its final, public report sometime in December. After that, either party would be entitled to appeal the report to the WTO Appellate Body.

¶47. (SBU) U.S. imports of shrimp from India totaled about USD 253 million in 2006, down from USD 314 million in 2005. Imports in 2007 are running approximately 25 percent below the pace of imports in ¶2006. India supplies roughly 10 percent of U.S. shrimp imports.

EXPORT OF SPICES TO THE U.S.

¶48. (SBU) The export of spices to the U.S. is in the form of spice powder and extract and is not as controversial as the export of shrimp. While products from some spice exporters have been found to be contaminated with artificial color and infectious organisms, the reputed companies have enjoyed an increase in exports to the U.S. You will visit two spice exporters in the city of Cochin, AVT McCormick and Synthite Chemical Industries. AVT McCormick is a joint venture with Baltimore-based McCormick Spices. Synthite Chemicals exports extracts of spices to several U.S. food processing companies. In addition to visiting the facilities of these companies, you will meet with spice exporters and visit the Port facility in Cochin.

¶49. (SBU) Unlike the trade-related issues with the shrimp industry, spice exporters are welcoming safety guidelines that would govern the export of spices to the U.S. Some spice exporters are not happy with the Spices Board conducting laboratory analysis of their products. AVT McCormick and Synthite Chemicals state that their in-house laboratories are better equipped and staffed as compared to the laboratories of the Spices Board.(Note. The Ministry of Health and Family Welfare has no direct oversight on Indian spices exports, nor does the Ministry of Agriculture have direct oversight of pesticides use of post harvest practices, per se.

¶50. (SBU) According to the Spices Board, Ministry of Commerce, the total export figures for spices from India was USD 125 million in 2005, USD 145.6 million in 2006, and USD 164 million (provisional) in 2007 (exchange of Rupees 40 = 1USD). The total quantum of spice

exports in the corresponding years is 42,402 tons in 2005; 43,243 tons in 2006; and 46,935 tons in 2007. The total export for spices to the U.S. market is estimated to rise to 79,580 tons with a value of USD 437 million in 2008.

SAFETY OF PHRAMACEUTICALS

¶51. (SBU) The Indian pharmaceutical industry has a mixed record of performance on safety. While name brand finished product pharmaceutical companies have a good safety record and follow international norms, many pharmaceutical companies that cater to domestic and unregulated international markets do not follow rigorous safety protocols. Counterfeit and spurious drugs produced by small time manufacturers, mostly in the northern states of Uttar Pradesh, Bihar, and Punjab, has been recognized as a problem by the Ministry of Health and Family Welfare. Lack of jurisdiction by central drug authorities over state regulatory systems has allowed growth of this industry in India. Brand name companies and pharmaceutical trade associations have in-house systems to counter counterfeit and spurious drug production, which includes coordinating with police in conducting raids on shops and small size companies.

¶52. (SBU) In Nov. 2007, generic major manufacturer Ranbaxy, India's largest pharmaceutical company, announced a voluntary recall of 73 million tablets of its 600 milligram and 800 milligram dosages of Gabapentin from the U.S. retail market after discovering impurities outside the approved specification limit. This is not the first of Ranbaxy's FDA problems. In June 2006, FDA raised questions on its Paonta Sahib plant. In Feb. 2007, FDA shut down Ranbaxy's US headquarters, located in New Jersey.

¶53. (SBU) India has the largest number of Active Pharmaceutical Ingredient (API) producing companies in the world, with many of them producing APIs for U.S. pharmaceutical companies. The bulk APIs for HIV/AIDS drugs are made in India for Indian generic manufacturers use and for the use of generic and brand name manufacturers in the United States.

INDIAN RESPONSE TO IMPORT SAFETY

¶54. (SBU) We believe that in your meetings with Ministers and other government officials, you will be hear the steps India is taking to

ensure the safety of drugs and food produced in India for domestic and international markets. You will also be told that products from Indian companies are safer and better as compared to consumer products from China. Despite this public posturing, they will be eager to hear your views and entertain the proposal to establish a bilateral agreement on import safety. They would also be eager to talk to you about the new authorities GOI is establishing for drugs, food, devices, and biotechnology. They will also seek technical assistance from FDA, and likely urge FDA to pre-clear food exports to the U.S. and/or accept industry testing or self inspection.

¶55. (SBU) The export of agricultural products and pharmaceuticals is governed and regulated by several Ministries. While the industry has to follow technical norms developed by Ministry of Health and Family Welfare (for finished drugs), Ministry of Chemicals and Fertilizers (for bulk drugs), Ministry of Environment (for recombinant products), Ministry of Science and Technology (for biotechnology products), the Ministry of Commerce is the key Ministry as far as export of products are concerned. The Ministry of Commerce provides incentives, support, and regulation through independent boards. This complicated system of inter-ministerial decision making makes it difficult for Indian policy makers to achieve consensus in a timely manner.

¶56. (SBU) Compared to the governmental view and response, industry leaders of the food and pharmaceutical sectors are eager to develop standard operating procedures that would satisfy regulators in the

United States for import. Some industry leaders, especially from the shrimp and horticulture industry, have publicly stated that the U.S. is placing "excessive" safety requirements on them, but privately admit the need to institute safety procedures.

¶57. (SBU) According to Mr. Vijay Topa of the Federation of Indian Chambers of Commerce and Industries (FICCI), many industry leaders view following best practices in their interest not only for expanding their export to the United States, but also to other countries and the domestic market. One industry leader told Mission Health Attach that there is domestic and international "market value" for stating "safety norms followed as per FDA regulations". However, FICCI, like the GOI, would like to emphasize testing rather than a systemic approach to import safety by its own laboratory

YOUR MEETINGS WITH INDIAN LEADERS

¶58. (SBU) We suggest that in your meetings with different Ministers and the Prime Minister, you convey the following messages: 1) we value the existing productive and vibrant partnership on health sciences and public health; 2) we seek to increase technical collaboration and capacity building through HHS, USAID, and USDA; 3) there is value and a need for science and data-based prompt and transparent decision making; 4) the safety of consumer products, such as drugs and food, is a public health issue in the interest of India and the United States; and 5) India and the United States, two knowledge-based economies, can set examples for other countries to follow regarding the safety of consumer products.

MEETING WITH THE PRIME MINISTER

¶59. (SBU) We suggest you:

¶1. Congratulate and thank the Prime Minister for his "Concept of One Health Based on Integrated Approach for Animal and Human Health", which he stated at the New Delhi Ministerial Meeting on Avian and Pandemic Influenza. You can inform the Prime Minister that your department has posted 10 scientists and public health experts to work with the Indian Ministry of Health and Science and Technology, including two on avian and seasonal influenza.

¶2. Thank the Prime Minister for his personal involvement in eradication of polio from the affected regions of Uttar Pradesh and Bihar. You should reiterate USG support for India's polio eradication through your department and USAID. We suggest you

propose that his government appoint a senior administrative official, who will exclusively focus on the administrative, management, logistic, and funding aspects of polio eradication.

¶3. Inform him that you met Health Minister Dr. Ramadoss in Chennai, where you and the Minister visited an HIV/AIDS hospital and a youth group that promotes education and awareness for HIV/AIDS in college students. You should tell him that you offered to the Minister technical support in conducting scientific workshops on Disease Burden Estimation, Control, and Prevention, with focus on cardiovascular disease, diabetes, mental health, malaria, and measles. You believe that we have the tools and technologies to fight, even eliminate, diseases like malaria and measles. We also need to get a better handle on chronic disease, such as heart disease, diabetes, and mental health, so that we can develop better control and prevention strategies. We have national and international experience in all these areas, and will be pleased to work with your Ministry of Health and Family Welfare.

¶4. Inform that American citizens, like Indian citizens, are cautious about safety of food, drugs, and other consumer products. They are expecting and demanding actions from political, policy, and technical leaders. The issue is pertinent to products made in the United States as well as products imported into the United States.

¶5. Inform you were in China last month and signed bilateral agreements that would allow agencies of our two governments to cooperate on safety of consumer products that are exported from China into the United States.

¶6. Inform that you have talked to Minister Ramadoss about the safety of drugs and food in Chennai and plan to meet other Ministers to discuss this issue. You can tell him you are meeting with the Ministers of Health, Agriculture, Commerce, Science and Technology, and External Affairs to initiate discussion on establishing bilateral agreements on Import Safety.

MEETING WITH THE MINISTER OF HEALTH AND FAMILY WELFARE

¶60. (SBU) This is your third meeting with the Minister of Health and Family Welfare Dr. Anbumani Ramadoss. The previous two meetings were in your office, when you signed bilateral agreements on HIV/AIDS and STD, Emerging and Reemerging Infectious Diseases, and Environment and Occupational Health. He will accompany you to the visit to the HIV/AIDS hospital and the Red Ribbon Club meeting at a local college. You will have a formal meeting with him at your hotel.

¶61. (SBU) Based on information available to us, Minister Ramadoss is likely to seek technical assistance in a few areas. These areas and your suggested response is below:

¶1. Technical support from CDC for setting up a tobacco laboratory.

Suggested response: CDC is collaborating with the ICMR's National Institute of Occupational Health in Ahmedabad. We sent a technical team early this year and they visited a few institutions and submitted a report to ICMR. I understand there have been some delays in getting some projects started, which may be due to a change in leadership of the institute. We are eager to collaborate on this activity with you and provide technical assistance.

¶2. Technical support from CDC for Integrated Disease Surveillance Program

Suggested response: This topic is important to me. Dr. Julie Gerberding reported to me your meeting with her and the commitment she made to send a technical team to review your disease surveillance project. As you know the team spent 2 weeks in India and a report was submitted to you. We remain your committed partners in the fight against emerging and remerging disease as well as chronic diseases. I believe MOH, World Bank, and CDC should

partner together to develop the best disease surveillance program possible. I understand that a team from your National Institute of Communicable Diseases has been invited to visit CDC. This is a good collaboration and having your technical staff meet with our staff is the best way to share experiences.

¶3. Technical help from FDA for setting up the Central Drug Authority and the Food Safety and Standards Authority

Suggested response: I would have the Commissioner of FDA respond. FDA Commissioner's response: Mr. Minister, I am aware of your meetings with my predecessors on this topic. I am pleased to note the progress of your Ministry in establishing the authority on food and drugs. I would like to suggest you have someone, preferably a technical leader, communicate with Dr. Lumpkin on specific needs. This will allow us to find someone at the FDA or recommend someone from FDA alumni who could provide help to your officials. Please note that we are eager to find more information and are ready to assist.

¶4. Technical cooperation from NIH in establishing a program on low cost health care devices

Suggested Response: NIH has recently signed a bilateral agreement with the Ministry of Science and Technology on Low Cost Health Technologies. I think partnering with the Ministry of Health and Family Welfare is a natural extension of this new collaboration. I will convey this message to Dr. Zerhouni.

¶5. Continued support from CDC for polio.

Suggested response: I am aware of the challenge you face, both at the national and international level. I would like to thank you for your leadership and courage to keep the focus on your program. I commit to continued support from the United States government. There is commitment to stay with you till you eliminate polio from India. You have some of my finest polio experts from CDC working through WHO on the polio elimination program. Sometimes I think of what I would do if this was a problem in the United States. There are no easy solutions, buy we know that vaccination has worked in India and other countries where polio was endemic. So lowering the guard is not an option. As a strategy, I would propose you appoint a senior official in your Ministry responsible for all management, logistic, and funding aspects of the polio elimination program. This person should only work on polio, so she/he could give 100 percent of his/her time to the project. Such a position, dedicated solely to polio eradication, may increase the effectiveness of your program.

ADDITIONAL SUGGESTIONS

¶62. (SBU) I would like to congratulate you on hosting a successful New Delhi Ministerial Meeting on Avian and Pandemic Influenza last month. Because of last minute administrative reasons I could not attend the meeting, but Ambassador John Lange reported on the meeting. From all accounts I heard, it was a successful meeting. Also, congratulate him for a successful CODEX meeting on Food Hygiene jointly chaired with the U.S.

¶63. (SBU) I would like to talk to you about the safety of drugs and food that are exported to the United States. As you know, we had import safety problems with some consumer products from China. There have been similar incidences of product safety in the case of shrimp, spices, and more recently with generic drugs from Ranbaxy. One of my purposes in visiting India is to meet with government leaders and industry leaders, so that I can talk about import safety. I was in China last month and signed agreements that would allow agencies of our two governments to work towards the safety of consumer products. I would like to initiate a discussion with you and your counterparts in other Ministries on establishing agreements on import safety.

¶64. (SBU) I am pleased that your Ministry is establishing

independent authorities on drugs and food. There is a need for such authorities and it would be appropriate for our two regulatory agencies to cooperate to ensure the safety of products. I recognize there is involvement of multiple Ministries in the case of food exports, and I am hoping to talk to your Ministers of Agriculture and Commerce, so that I can get their views as well.

¶65. (SBU) Mr. Minister, drug and food safety is a human health issue. You know this better than many people engaged in administering health programs. American citizens, like Indian citizens, demand safe drugs, vaccines, medical devices, food, and other consumer products. It is their right to demand products that would not harm them, and it is our responsibility to provide safe drugs, vaccines, devices, and food to them. For us it is a domestic and international issue. It is an international issue, because we import a large quantity of drugs from China and India. Therefore, there is a need to work together to make sure that the products we import and/or export are safe as determined by the best available science and methodology.

MEETING WITH THE MINISTER OF SCIENCE AND TECHNOLOGY

¶66. (SBU) Your meeting with Mr. Kapil Sibal, Minister of Science and Technology has not been confirmed. He will be out of Delhi, but we can schedule meeting with Secretary of Biotechnology. Our suggestions for this meeting are:

¶1. I am pleased that your Ministry and the agency of my Department are engaged in some excellent life sciences and health sciences projects. We should take pride in our partnership and congratulate our scientists.

¶2. The example of rota virus vaccine development is a good example of our collaboration. If this vaccine, which is being developed by an Indian company with technical support from CDC and NIH, works we will be able to prevent hundreds of thousands of children in India and around the world from dying.

¶3. I understand that your Ministry has plans to establish centers for Translational Research. I am aware of the discussions your scientists have had with scientists of NIH on this topic and there is an interest in establishing a bilateral agreement. This collaboration should include training and collaborative opportunities in laboratories in both countries. I would like to see your scientists working in our laboratories and our scientists working in your laboratories. I think answers to some of most complex questions will come from international collaborations, so I support this new initiative.

¶4. I would like to talk to you about the safety of drugs and food that are exported to the United States. I visited Dr. Reddy's pharmaceutical company and Bharat Biotech International Limited in Hyderabad on Tuesday, where I had an opportunity to talk about import safety. As you know, we had import safety problems with some consumer products from China. One of my purposes of visiting India is to meet with government and industry leaders so that I can talk about import safety. I was in China last month and signed agreements that would allow agencies of our two governments to work towards the safety of consumer products. I would like to initiate a discussion with you and your counterparts in other Ministries on establishing agreements on import safety.

¶5. I am pleased that your Ministry is establishing independent authorities on medical devices and biotechnology. There is a need for such authorities and it would be appropriate for our two regulatory agencies to cooperate to ensure the safety of products. I recognize there is involvement from multiple Ministries in the case of drugs and food exports, and I am hoping to talk to your Ministers of Agriculture and Commerce so that I can get their views as well.

¶6. Mr. Minister, the safety of medical devices, drugs, and food is a human health issue. American citizens, like Indian citizens,

demand safe drugs, vaccines, devices, food, and other consumer products. It is their right to demand products that would not harm them, and it is our responsibility to provide safe drugs, vaccines, devices, and food to them. For us it is a domestic and international issue. It is an international issue, because we import a large quantity of drugs from China and India. Therefore, there is a need to work together to make sure that the products we import and/or export are safe as determined by the best available science and methodology.

MEETING WITH MINISTER OF COMMERCE

¶67. (SBU) Your meeting with Minister Kamal Nath has been confirmed. This is a critical Ministry for export of food to the United States. This Ministry does not have technical expertise, but they are involved in regulating and promoting export of food through independent entities that are headed by Ministry of Commerce officials. We suggest you share information on the existing and

growing U.S.-India collaboration on health sciences and then talk about import safety. This Minister would not be adequately briefed on the large portfolio of U.S.-India health activities, so sharing what we do with India on health will be of strategic value for this meeting. We believe Minister Nath will welcome developing norms that ensure safety of food, but he may state that they have safety regulations in place. You should mention to him that you visited two spice exporters in Cochin and met with leaders of the food and drug industry at FICCI earlier today.

¶68. (SBU) He would know that you have signed bilateral agreements with China on import safety, so you should state that one of your purposes of visiting India is to meet with government and industry leaders for discussions on import safety. We believe that this Ministry may be our initial counterpart Ministry for establishing a bilateral agreement on food safety, so continuation of discussion with this Minister and his ministry officials will be important over the next few months. Import safety -including food and agricultural products-has been discussed at both the technical and political level in the U.S.-Indo Trade Policy Forum (TPF). The TPF is a Presidential initiative, chaired by the U.S. Trade Representative and the Indian Ministry of Commerce. However, real import safety will be achieved only if/when the Ministry of Commerce cooperates with the line Ministries and provides enforcement rather than more tests as a way to ensure import safety.

¶69. (SBU) We suggest you discuss the import safety of food in the context of a human health issue, where food safe from diseases and harmful chemicals have to me assured to consumers. You should state that American citizens, like Indian citizens, demand safe drugs, vaccines, medical devices, food, and other consumer products. It is their right to demand products that would not harm them, and it is our responsibility to provide safe food to them. For us it is a domestic and international issue. It is an international issue, because we import a large quantity of drugs from China and India. Therefore, there is a need to work together to make sure that the products we import and/or export are safe as determined by the best available science and methodology.

MEETING WITH MINISTER OF AGRICULTURE

¶70. (SBU) Your meeting with Minister of Agriculture Mr. Sharad Pawar is not confirmed yet, but we expect it be confirmed. Mr. Pawar is a senior politician, whose party is a coalition member of the Congress Party-led UPA government. He is generally not well informed on technical issues, but is known to protect the interests of farmers irrespective of the issue or the facts. We also suggest a strategy similar to one we have proposed for your meeting with the Minister of Commerce, where you first talk about the rich history of collaboration followed by a discussion on import safety.

¶71. (SBU) As far as collaboration with this Ministry is concerned; you should highlight the importance of the U.S.-India Agriculture Knowledge Initiative between USDA/USAID and the Indian Ministry of

Agriculture.

¶72. (SBU) You should congratulate him for a successful New Delhi Ministerial Conference on Avian and Pandemic Influenza, which he co-chaired with Minister Ramadoss.

¶73. (SBU) We suggest you discuss the import safety of food in the context of a human health issue, where food safe from diseases and harmful chemicals have to me assured to consumers. You should state that American citizens, like Indian citizens, demand safe drugs, vaccines, medical devices, food, and other consumer products. It is their right to demand products that would not harm them, and it is our responsibility to provide safe food to them. For us it is a domestic and international issue. It is an international issue, because we import a large quantity of drugs from China and India. Therefore, there is a need to work together to make sure that the products we import and/or export are safe as determined by the best

available science and methodology.

¶74. (SBU) We look forward to your productive visit and stand ready to support you and your delegation in Chennai, Hyderabad, Cochin and Delhi.

WHITE